IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

NEODIAGNOSTIX, INC.	)
	)
Plaintiff,	)
	) Civil Action No. __________
v.	)
	) **JURY TRIAL DEMANDED**
QUEST DIAGNOSTICS, INC.,	)
	)
Defendant.	)
	)

COMPLAINT

Plaintiff NeoDiagnostix, Inc. ("NeoDiagnostix"), brings this civil action against Defendant Quest Diagnostics, Inc. ("Quest" or "Defendant") for patent infringement. For its Complaint, by and through the undersigned counsel, NeoDiagnostix alleges as follows:

NATURE OF THE ACTION

1. NeoDiagnostix brings this action seeking injunctive and monetary relief for injury and damages caused by Quest. NeoDiagnostix is a pioneer in the development of cervical cancer diagnostic testing using genetic technologies. Quest offers a competing diagnostic test for cervical cancer that infringes several of NeoDiagnostix's patents. In 2016, in connection with discussions relating to a potential business arrangement, NeoDiagnostix offered Quest a license to its patents, which Quest declined. NeoDiagnostix has thus filed this action to protect its intellectual property rights and stop Quest's continued knowing, willful, malicious and deliberate infringement of NeoDiagnostix's patents.

THE PARTIES

2. NeoDiagnostix is a Delaware corporation with a place of business located at 910 Clopper Road, Suite 240S, Gaithersburg, MD 20878.

3. Upon information and belief, Quest is a Delaware entity with a place of business located at 3 Giralda Farms, Madison, New Jersey 07940.

JURISDICTION AND VENUE

4. This action arises under the Patent Act, 35 U.S.C. § 1 *et seq.*

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

6. Upon information and belief, Defendant conducts substantial business in this forum, directly or through intermediaries, including: (i) at least a portion of the infringements alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct and/or deriving substantial revenue from goods and services provided to individuals in this district. Indeed, upon information and belief, Quest has a number of patient service centers in this District, which offer the infringing test. Thus, venue is proper in this district pursuant to §§ 1391(b) & (c) and 1400(b).

BACKGROUND FACTS

NEODIAGNOSTIX INVENTS NOVEL TEST FOR CERVICAL CANCER

7. NeoDiagnostix is a cancer diagnostics company with an emphasis in women's health. NeoDiagnostix was founded in January 2005 by two scientists, Gregory Endress and Dr. Madhvi Upender, along with some individual investors, to develop and provide cancer diagnostic testing services using genetic technologies. Prior to launching NeoDiagnostix, Mr. Endress had significant experience as a research scientist and business leader in the life sciences area, particularly involving the use of genes to predict, detect, treat and cure human diseases such as cancer, and Dr. Upender had significant research experience specifically in cancer genetics. At the

time NeoDiagnostix was founded. Mr. Endress served as its first President and Chief Executive Officer, later becoming its Chief Scientific Officer, a position he holds today.

8. Through Mr. Endress, Dr. Upender and its other scientists, NeoDiagnostix possesses highly specialized experience and skills in the area of Fluorescence *In Situ* Hybridization ("FISH") techniques and has developed and markets novel, proprietary genetic FISH tests for the diagnosis, prognosis and treatment of cancer. By detecting genetic changes in cells, NeoDiagnostix's tests can quickly and accurately identify cancerous cells at earlier stages than traditional testing methods, enabling early intervention in cervical cancer treatment. Since the company was launched in 2005, NeoDiagnostix spent over 10 years and millions of dollars in developing and improving the application of FISH technology to develop a rapid and accurate diagnostic test for cervical cancer, determining which patients would benefit from such testing, and educating and developing the market for this unique test.

DEVELOPMENT OF NEODIAGNOSTIX'S CERVICAL DNA DTEX® TEST

9. NeoDiagnostix's flagship Cervical DNA Dtex® test identifies permanent and irreversible damage to cervical cells as a result of a persistent human papilloma virus (HPV) infection. With the additional genetic insight made possible by the Cervical DNA Dtex® test, clinicians are able to make more informed decisions about patient management and treatment, leading to earlier diagnoses of advanced stage disease, fewer unnecessary medical procedures and improved overall outcomes for patients.

10. NeoDiagnostix's Cervical DNA Dtex® test is a novel, proprietary and patented clinical laboratory test that uses FISH to identify chromosomal abnormalities within the DNA of a patient's cervical cells. The test is used in the management of women with high risk HPV infections or with mild cytological abnormalities identified through pap testing, such as Atypical

Squamous Cells of Unknown Significance (ASCUS) or Low Grade Squamous Intra-Epithelial Lesion (LSIL). A high risk HPV infection is required for the development of cervical cancer, although the majority of HPV-infected women never develop cervical cancer. Therefore, it is important to reliably identify those HPV infected women who have developed abnormal cervical cells that are the precursors to cervical cancer.

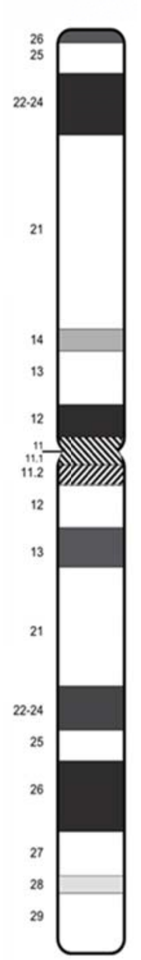
11. During persistent HPV infections, the virus produces viral proteins that disrupt a normal cell's function leading to instability of the cervical cell genome. This genomic instability results in permanent DNA damage and the development of chromosomal abnormalities that promote carcinogenesis. The gain (or "amplification") of the chromosomal region – in other words, the addition of extra DNA sequences - at chromosome locus 3q26 is typically the first abnormality to develop.

12. The human genome is made up of 23 pairs of chromosomes, numbered 1-23. Each chromosome has a short (labeled "p") and a long arm (label "q"). Scientists have subdivided these chromosomes into regions (called "bands") and numbered these bands, starting from the center of the chromosome (called the "centromere") to the end of the arm. Below is a representative illustration of a chromosome, identifying the short arm, the long arm, the centromere and the band numbering:

t

omer

g



osome 3

As shown by this figure, a probe targeting chromosome 3q26, would specifically bind (*e.g.*, "hybridize") to chromosome 3 at position q26.

13. As a cervical cell progresses to a cancerous cell, the amount of DNA damage increases and frequently results in the gain of additional DNA sequences. These amplified chromosome regions can be identified using FISH probes that bind (or hybridize) to a specific chromosomal band or locus. FISH probes used to detect the centromere are typically called CEN or CEP probes along with the specific chromosome they detect, *e.g.* a CEN3 or CEP3 FISH probe detects the number of chromosome 3 copies present in a cell.

14. The amplified regions on chromosome 3q26 are large and encompass multiple genes. Some genes located in these regions encode proteins that provide cells with a growth advantage when amplified resulting in the development of cancerous cells. The TERC gene located at 3q26 encodes a protein that interact and help the cell live longer and, eventually, become cancerous. The gain of the chromosomal regions, such as 3q26, occurs frequently in many cancers. Identification of these and other chromosomal abnormalities in women with HPV infections or with mild ASCUS/LSIL cytological abnormalities enables more effective management of these patients.

15. NeoDiagnostix's prototype Cervical DNA Dtex® test took approximately two and a half years to develop. NeoDiagnostix launched the first Cervical DNA Dtex® test in 2007, and since the launch, NeoDiagnostix has released a number of "improved" Cervical DNA Dtex® tests to improve the performance of and increase the efficiencies in the Cervical DNA Dtex® test.

NEODIAGNOSTIX CREATES THE MARKET
FOR DNA TESTS TO DETECT CERVICAL CANCER

16. When NeoDiagnostix launched its first Cervical DNA Dtex® test in 2007, many clinicians recognized the limitations of the existing diagnostic tests used in the screening and management of cervical cancer risk, but were otherwise unaware of the work in which NeoDiagnostix had been engaged for the past 2-1/2 years to develop a better alternative. Thus, when it was introduced in 2007, the Cervical DNA Dtex® test was the first of its kind and NeoDiagnostix was a pioneer in developing not only the test itself, but the market for such tests. NeoDiagnostix thus had to invest considerable time and effort in educating doctors about the clinical value of the Cervical DNA Dtex® test, and gaining the doctors' support to try the new test with their patients. NeoDiagnostix also had to work with these clinicians to demonstrate how the test would positively impact the management and health outcomes of the patient. This sales and

marketing process took several years to develop and refine, and was informed by NeoDiagnostix's investment in a large clinical study, along with feedback obtained from a number of practicing physicians that began ordering the test for patients considered at increased risk of developing cervical cancer based upon abnormal cytology findings.

17. NeoDiagnostix's sales and marketing efforts, particularly in the period of 2009 to the present, led to a record growth in the number of Cervical DNA Dtex® tests performed by NeoDiagnostix's laboratory, which increased 1300% from 2009 to 2016.

NEODIAGNOSTIX'S PATENT PORTFOLIO

18. Having invested considerable time and expense in developing its intellectual property, NeoDiagnostix has sought to protect its investment through patent protection, among other means, filing its first provisional patent application in 2008. Since 2008, a number of the inventions developed by NeoDiagnostix's scientists have been filed with the United States Patent and Trademark Office ("USPTO"), examined, and recognized as inventive by the USPTO through the issuance of seven (7) U.S. patents to date ("NeoDiagnostix Patent Portfolio"), three (3) of which are being asserted against Quest here ("NeoDiagnostix Asserted Patents").

19. The NeoDiagnostix Patent Portfolio includes U.S. Patent No. 8,748,099 (the "'099 patent"), entitled *"Method for the Cytological Analysis of Cervical Cells,"* which was duly and lawfully issued by the USPTO on June 10, 2014. A true and correct copy of the '099 patent, which is one of the NeoDiagnostix Asserted Patents, is attached hereto as Exhibit A.

20. The claims of the '099 patent are directed to methods of detecting chromosomal abnormalities in a cervical sample utilizing probes hybridizing to at least 3q and a control chromosome, with additional dependent claims to specified 3q probes (*e.g.*, probes that hybridize to 3q26, 3q26.2, or TERC), and centromere 3 probes (e.g., CEP3) and their use in FISH.

21. The NeoDiagnostix Patent Portfolio also includes U.S. Patent No. 9,080,203 (the "'203 patent"), entitled *"Method and System for Automated Image Analysis in Cancer Cells,"* which was duly and lawfully issued by the USPTO on July 14, 2015. A true and correct copy of the '203 patent, which is one of the NeoDiagnostix Asserted Patents, is attached hereto as Exhibit B.

22. The claims of the '203 patent are directed to methods of detecting chromosomal abnormalities in a cervical sample utilizing specific 3q probes hybridizing to chromosomal loci identified as EVI1 or MDS1, with additional dependent claims utilizing probes that hybridize to additional chromosomal 3q loci (*e.g.*, probes that hybridize to TERC, APRM1, MYNN, LRRC34, PIK3CA, PRKCI, SAMD7, LOC1000128164, SEC62, GPR160, and/or PHC3), and their use in FISH.

23. The NeoDiagnostix Patent Portfolio also includes U.S. Patent No. 9,562,270 (the "'270 patent"), entitled *"Method for the Cytological Analysis of Cervical Cells,"* which was duly and lawfully issued by the USPTO on February 7, 2017. A true and correct copy of the '270 patent, which is one of the NeoDiagnostix Asserted Patents, is attached hereto as Exhibit C.

24. The claims of the '270 patent are directed to methods of detecting chromosomal abnormalities in a cervical sample utilizing probes that hybridize to at least 3q and a centromere, the scoring of the probe signals, and the reporting of the status of the samples along with additional dependent claims utilizing probes that hybridize to additional chromosomal 3q loci (*e.g.*, probes that hybridize to EVI1, MDS1, TERC, APRM1, MYNN, LRRC34, LRRIQ4, LRRC31, SAMD7, LOC1000128164, SEC62, GPR160, PHC3, and/or PRKCI).

25. NeoDiagnostix is the assignee and owner of the right, title and interest in and to each of the patents included in the NeoDiagnostix Patent Portfolio (listed above), including the

right to assert all causes of action arising under the NeoDiagnostix Asserted Patents and the right to any remedies for infringement of them. Mr. Endress, NeoDiagnostix's Chief Scientific Officer, is one of the named inventors on the patents, along with Dr. Upender and two other current or former NeoDiagnostix employees.

NEODIAGNOSTIX'S INTERACTIONS WITH QUEST

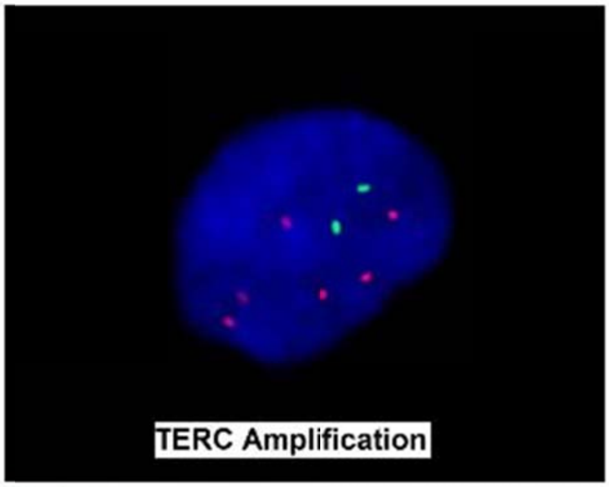
26. Upon information and belief, Quest is a national clinical laboratory offering a broad range of testing services throughout the country, including in this District. Upon information and belief, on or about August 30, 2012, Quest began offering its Cervical Cancer TERC test ("Quest's Cervical Cancer TERC Test"), a competing test to NeoDiagnostix's Cervical DNA Dtex® test. Quest describes its Cervical Cancer TERC Test on its website as follows:

Cervical Cancer, TERC, FISH
Test code(s) 91027

Survey ▸

Question 1. What is the Cervical Cancer, *TERC*, FISH assay?

This is a fluorescence in situ hybridization (FISH)-based assay performed using ThinPrep® or SurePath™ cervical cytology samples. This test determines the number of copies of *TERC*, a telomerase RNA component gene located at chromosome band 3q26. Two fluorescent probes are used to calculate a ratio between copy number for chromosome 3, measured by a peri-centromeric probe (green signals below), and the copies of the *TERC* gene locus (red signals below). The pattern of these two probes in each cell can thus be scored as non-amplified, TERC-amplified, or polysomic. Interpretation is based on the pattern and number of cells with either abnormal pattern.



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http://education.questdiagnostics.com/faq/FAQ57 (last accessed March 22, 2017). Upon information, this is a true and correct description of Quest's Cervical Cancer TERC Test.

27. On or about May 25, 2016, NeoDiagnostix and Quest began to discuss a potential business relationship between the companies whereby NeoDiagnostix would collaborate with Quest to enhance Quest's Cervical Cancer TERC Test.

28. On or about June 2, 2016, NeoDiagnostix conducted a webconference with Quest and provided Quest with a list of the NeoDiagnostix's patents and a summary of the claims of the patents. A copy of the slide materials, including a summary of NeoDiagnostix's patents and claims, was sent to Quest following the web conference.

29. On or about August 31, 2016, Quest informed NeoDiagnostix that it did not want

to collaborate with NeoDiagnostix on offering an enhanced test. NeoDiagnostix then explained to Quest that, in order for Quest to continue to offer and perform Quest's Cervical Cancer TERC Test, Quest would need a license to NeoDiagnostix's Patent Portfolio. Quest declined to discuss taking a license to any of NeoDiagnostix's patents.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 8,748,099
(under the Patent Act, 35 U.S.C. § 1 *et seq.*)

30. NeoDiagnostix repeats and realleges the allegations of paragraphs 1 through 29 as if fully set forth herein.

31. Without license or authorization and in violation of 35 U.S.C. § 271(a), Quest has infringed at least independent Claim 1 and dependent Claims 2-7 and 15-19 of the '099 patent by making, using, importing, offering for sale, and/or selling Quest's Cervical Cancer TERC Test.

32. Claim 1 recites a method of detecting chromosomal abnormalities in a plurality of cervical cells utilizing probes that hybridize to at least 3q and a sequence on a control chromosome and has a "threshold" limitation, reporting a lack of chromosomal abnormalities when a gain of 3q copy number is in less than 0.9% of the cells. ("Claim 1 Threshold of Patent '099"). Claim 2 further defines scoring of the chromosomal copy number as being performed by counting the cells having chromosomal abnormalities. Claim 3 further defines scoring of the chromosomal copy number as being performed by counting hybridization signals. Claim 4 further defines the targeted chromosome 3q nucleic acid sequence as including the locus 3q26. Claim 5 further defines the targeted chromosome 3q nucleic acid sequence as including the locus 3q26.2. Claim 6 further define the targeted chromosome 3q nucleic acid sequence as including the chromosomal locus identified as TERC. Claim 7 further defines the targeted control chromosome targeted sequence as centromere 3 (CEN3). Claim 15 further defines the method as comprising different methods of detecting, including FISH. Claim 16 further defines the sample as comprising cells derived from

a cervical biopsy, a punch biopsy, a pap smear, a thin layer cytology specimen, a thin layer suspension, a fine needle aspiration, a loop electrosurgical excision procedure (LEEP), a hysterectomy, a CONE biopsy, and/or an endocervical curettage (ECC). Claim 17 states that at least 800 cells are examined. Claim 18 states that at least 1000 cells are examined and Claim 19 states that 1000 cells are examined

33. Upon information and belief, Quest's Cervical Cancer TERC Test meets all of the limitations of Claim 1 of the '099 patent. More specifically, it is a FISH test that uses a 3q probe and a control sequence to examine and detect increased numbers or "gains" in the 3q region. In this regard, Quest's Cervical Cancer TERC Test includes the following steps: (1) hybridizing a first nucleic acid sequence to a target nucleic acid sequence on chromosome 3q; (2) hybridizing a second nucleic acid sequence to a target nucleic acid sequence on a control chromosome; (3) detecting a hybridization signal of the first and the second nucleic acid sequence, wherein the hybridization signal of said first and the second nucleic acid sequences is indicative of chromosomal copy number for chromosome 3q and the control chromosome; and (4) scoring the chromosomal copy number for chromosome 3q. In addition, upon information and belief, Quest's performance of its Cervical Cancer TERC Test also meets the recited threshold of Claim 1 because many patients who have been reported as having no chromosomal abnormalities under Quest's reporting cut-offs would also be reported as having a lack of chromosomal abnormalities under the Claim 1 Threshold of the '099 Patent – thereby infringing this claim limitation.

34. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 2, since Claim 2 depends from Claim 1, *see supra* Paragraph 33 and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 2 in that Quest's Cervical Cancer TERC Test is performed by counting the cells having chromosomal abnormalities.

35. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 3, since Claim 3 depends from Claim 1, *see supra* Paragraph 33, and the Quest Cervical TERC Test meets the added limitation of Claim 1 in that Quest's Cervical Cancer TERC Test is performed by counting hybridization signals.

36. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 4, since Claim 4 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 4 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as 3q26.

37. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 5, since Claim 5 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 5 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as 3q26.2.

38. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 6, since Claim 6 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 6 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences at the chromosomal 3q locus identified as TERC.

39. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 7, since Claim 7 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 7 in that the control chromosome

probes used in Quest's Cervical Cancer TERC Test hybridize to the centromere of chromosome 3 (CEN3).

40. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 15, since Claim 15 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 15 in Quest's Cervical Cancer TERC Test utilizes FISH as a method of detection.

41. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 16, since Claim 16 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 16 in Quest's Cervical Cancer TERC Test detects cells derived from at least pap smears and thin layer cytology specimens.

42. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 17, since Claim 17 depends from Claim 1, *see supra* Paragraph 33, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 17 in that at least 800 cells have been examined when performing Quest's Cervical Cancer TERC Test.

43. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 18, since Claim 18 depends from Claim 17, *see supra* Paragraph 42, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 18 in that at least 1000 cells have been examined when performing Quest's Cervical Cancer TERC Test.

44. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 19, since Claim 19 depends from Claim 18, *see supra* Paragraph 43, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 19 in that 1000 cells have been examined when performing Quest's Cervical Cancer TERC Test.

45. NeoDiagnostix is entitled to recover from Defendant the damages sustained by NeoDiagnostix as a result of Defendant's infringement of the '099 patent in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

46. NeoDiagnostix is also entitled to an injunction preventing all further sale or use of Quest’s Cervical Cancer TERC Test , or any method claimed in the ‘099 patent for detecting chromosomal abnormalities.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,080,203
(under the Patent Act, 35 U.S.C. § 1 *et seq.*)

47. NeoDiagnostix repeats and realleges the allegations of paragraphs 1 through 46 as if fully set forth herein.

48. Without license or authorization and in violation of 35 U.S.C. § 271(a), Quest has infringed at least independent Claim 1 and dependent Claims 2-7, 10, 12-15, 18, 20-22, 25, 27-33 of the '203 patent by making, using, importing, offering for sale, and/or selling Quest’s Cervical Cancer TERC Test .

49. Claim 1 recites an automated method of detecting chromosomal abnormalities in a plurality of cells in a cervical sample utilizing specific 3q probes that hybridize to a target comprising either one of the chromosome 3q specific loci EVI1 or MDS1, and reporting whether a sample contains chromosomal abnormalities when a particular “threshold” is met. In Claim 1, the “threshold” is defined as wherein the sample is determined to be negative or have normal ploidy when a gain of chromosomal copy number is in less than 0.9% of the cells (“Claim 1 Threshold of the ‘203 Patent”). Claim 2 further defines scoring of the chromosomal copy number as being performed by counting the cells having chromosomal abnormalities. Claim 3 further defines scoring of the chromosomal copy number as counting hybridization signals. Claim 4 further

defines the method as being performed using an automated microscope. Claim 5 further defines that the cells in the sample are deposited in a thin layer on a slide. Claim 6 further defines the method as comprising different methods of detecting, including FISH. Claim 7 defines that the target further comprises at least one of the chromosome 3q specific loci TERC, APRMl, or MYNN along with EVI1 or MDS1 (as recited in Claim 1). Claims 10, 18, and 25 (depending from Claims 7, 15 and 22 respectively) add a further probe that hybridizes to a nucleic acid sequence located at chromosome 3 centromere locus identified as CEN3/CEP3. Claims 12, 20, and 27 (depending from Claims 7, 15 and 22 respectively) state that at least 800 cells are examined. Claims 13, 21 and 28 (depending from Claims 7, 15 and 22 respectively) state that at least 1000 cells are examined. Claim 14, depending from Claim 7, further defines that the target comprises all three of chromosome 3q loci identified as TERC, APRM1 and MYNN along with EVI1 or MDS1 (as recited in Claim 1). Claim 15, depending from Claim 7, further defines that the target comprises LRRC34 along with (a) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (b) at least one of EVI1 or MDS1 (as recited in Claim 1). Claim 22, depending from Claim 15, further defines that the 3q26 target comprises at least one of SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1). Claim 29, depending from Claim 22, further defines that the 3q26 target comprises all of the loci identified as SAMD7, LOC1000128164, SEC62, GPR160, and PHC3 along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1). Claim 30, depending from Claim 22, further defines that the 3q26 target comprises all of the loci identified as GPR160, PHC3 and PRKC1 along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1). Claims 31-33 (depending from Claims 7, 15 and 22 respectively) state that at least 50 cells are examined

50. Upon information and belief, Quest's Cervical Cancer TERC Test meets all of the limitations of Claim 1 of the '203 patent. More specifically, it is a FISH test that uses 3q probes to examine and detect increased numbers or "gains" in the 3q region (specifically EVI1or MDS1). In this regard, Quest's Cervical Cancer TERC Test includes the following steps: (1) hybridizing nucleic acid probes to a target, wherein the target comprises EVI1or MDS1; (2) detecting the hybridization signal of the nucleic acid probes, wherein the hybridization signal is indicative of chromosomal copy number for the target; and (3) scoring the chromosomal copy number of the target. In addition, upon information and belief, Quest's performance of their Quest Cervical TERC Test also meets the recited threshold of Claim 1 because many patients who have been reported as having no chromosomal abnormalities under Quest's reporting cut-offs would also be reported as a lack of chromosomal abnormalities under the Claim 1 Threshold of the '203 Patent. Upon information and belief, at least some of the foregoing steps are automated (*e.g.*, image capturing, scoring and reporting).

51. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 2, since Claim 2 depends from Claim 1, *see supra* Paragraph 50, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 2 in that Quest's Cervical Cancer TERC Test is performed by counting the cells having chromosomal abnormalities.

52. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 3, since Claim 3 depends from Claim 1, *see supra* Paragraph 50, and Quest's

Cervical Cancer TERC Test meets the added limitation of Claim 3 in that Quest's Cervical Cancer TERC Test is performed by counting hybridization signals.

53. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 4, since Claim 4 depends from Claim 1, *see supra* Paragraph 50, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 4 in that Quest's Cervical Cancer TERC Test is performed using an automated microscope.

54. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 5, since Claim 5 depends from Claim 1, *see supra* Paragraph 50, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 5 in that cells in the sample used in Quest's Cervical Cancer TERC Test are deposited in a thin layer on a slide.

55. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 6, since Claim 6 depends from Claim 1, *see supra* Paragraph 50, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 6 in Quest's Cervical Cancer TERC Test utilizes FISH as a method of detection.

56. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 7, since Claim 7 depends from Claim 1, *see supra* Paragraph 50, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 7 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences of at least one of the chromosomal 3q loci identified as TERC, ARPM1 or MYNN along with EVI1 or MDS1 as recited in Claim 1.

57. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claims 10, 18 and 25, since Claims 10, 18 and 25 depend from Claims 7, 15 and 22 respectively *see supra* Paragraph 56 and *see infra* Paragraphs 61 and 62, and Quest's Cervical

Cancer TERC Test meets the added limitation of Claim 10 in that Quest's Cervical Cancer TERC Test also uses probes that hybridize to nucleic acid sequences at the centromere 3 chromosomal locus identified as CEN3/CEP3.

58. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claims 12, 20, and 27, since Claims 12, 20 and 27 depend from Claims 7, 15, and 22 respectively *see supra* Paragraph 56 and *see infra* Paragraphs 61 and 62, and Quest's Cervical Cancer TERC Test meets the added limitation of Claims 12, 20 and 27 in that at least 800 cells have been examined when performing Quest's Cervical Cancer TERC Test.

59. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claims 13, 21, and 28, since Claims 13, 21 and 28 depend from Claims 7, 15, and 22 respectively *see supra* Paragraph 56 and *see infra* Paragraphs 61 and 62, and Quest's Cervical Cancer TERC Test meets the added limitation of Claims 13, 21 and 28 in that at least 1000 cells have been examined when performing Quest's Cervical Cancer TERC Test.

60. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 14, since Claim 14 depends from Claim 7, *see supra* Paragraph 56, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 14 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences that includes all three chromosomal 3q loci identified as TERC, ARPM1 and MYNN along with EVI1 or MDS1 as recited in Claim 1.

61. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 15, since Claim 15 depends from Claim 7, *see supra* Paragraph 56, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 15 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences that includes the

additional 3q locus identified as LRRC34 along with (a) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (b) at least one of EVI1 or MDS1 (as recited in Claim 1).

62. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 22, since Claim 22 depends from Claim 15, *see supra* Paragraph 61, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 22 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences of at least one of the chromosomal 3q loci identified as SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1).

63. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 29, since Claim 29 depends from Claim 22, *see supra* Paragraph 62, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 29 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to nucleic acid sequences that include all of the following chromosomal 3q loci identified as SAMD7, LOC1000128164, SEC62, GPR160 and PHC3 along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1).

64. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 30, since Claim 30 depends from Claim 22, *see supra* Paragraph 62, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 30 in that the 3q probes used in Quest's Cervical Cancer TERC Test also hybridizes to nucleic acid sequences that further include all three chromosomal 3q loci identified as GPR160, PHC3, and PRKCI along with (a) LRRC34 (as recited in Claim 15) and (b) at least one of TERC, APRM1 or MYNN (as recited in Claim 7) and (c) at least one of EVI1 or MDS1 (as recited in Claim 1).

65. Upon information and belief, Quest’s Cervical Cancer TERC Test also meets all the limitations of Claims 31-33, since Claims 31-33 depend from Claims 7, 15, and 22 respectively *see supra* Paragraphs 50, 61 and 62, and Quest’s Cervical Cancer TERC Test meets the added limitation of Claims 31-33 in that at least 50 cells have been examined when performing Quest’s Cervical Cancer TERC Test.

66. NeoDiagnostix is entitled to recover from Defendant the damages sustained by NeoDiagnostix as a result of Defendant's infringement of the '203 patent in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

67. NeoDiagnostix is also entitled to an injunction preventing all further sale or use of Quest’s Cervical Cancer TERC Test , or any method claimed in the ‘203 patent for detecting chromosomal abnormalities.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,562,270
(under the Patent Act, 35 U.S.C. § 1 *et seq.*)

68. NeoDiagnostix repeats and realleges the allegations of paragraphs 1 through 67 as if fully set forth herein.

69. Without license or authorization and in violation of 35 U.S.C. § 271(a), Quest has infringed at least independent Claim 1 and dependent Claims 2-12 and 17-19 of the '270 patent by making, using, importing, offering for sale, and/or selling Quest's Cervical Cancer TERC Test .

70. Claim 1 recites a method of reporting chromosomal abnormalities in a cervical sample wherein a first nucleic acid sequence is hybridized to a target nucleic acid sequence on chromosome 3q and a second nucleic acid sequence is hybridized to a target nucleic acid sequence on a centromere, the detection of the hybridization signals from both target sequences, the scoring of the chromosomal copy number for 3q and the centromere, and the reporting of the status of the samples using the scoring information based on a particular "threshold." In claim 1, an "abnormal threshold" is defined if the chromosomal copy number for 3q or the centromere is greater than 2 while a "normal threshold" is normal if chromosomal copy number of 3q is 2 and the centromere is 2. Once the thresholds are scored, the sample is reported as (1) "positive for chromosomal abnormalities" if 1.0% or more of the analyzed cells are scored as abnormal; or (2) "negative for chromosomal abnormalities" if less than 1.0% of the analyzed cells are scored as normal.

71. Claim 2 further defines the targeted chromosome 3q nucleic acid sequence as including locus 3q26. Claim 3 further defines the targeted chromosome 3q nucleic acid sequence as including locus3q26.2. Claim 4 further defines the targeted nucleic acid sequence on 3q being any one of EVI1, MDS1, TERC, APRM1, MYNN, LRRC34, LRRIQ4, LRRC31, SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI. Claim 5, depending of Claim 4, further defines the targeted chromosome 3q nucleic acid sequence as including the chromosomal locus

identified as TERC. Claim 6 further defines the targeted centromere nucleic acid sequence as centromere 3 (CEP3). Claim 7 further defines the determination of a cell to be abnormal if the chromosomal copy number for both 3q and the centromere is greater than 2. Claim 8, depending of Claim 7, further defines the targeted nucleic acid sequence on chromosome 3q as including the locus 3q26. Claim 9, depending on Claim 7, further defines the targeted chromosome 3q nucleic acid sequence as including the locus 3q26.2. Claim 10, depending on Claim 7, further defines the targeted nucleic acid sequence on 3q being any one of EVI1, MDS1, TERC, APRM1, MYNN, LRRC34, LRRIQ4, LRRC31, SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI. Claim 11, depending on Claim 7, further defines the targeted chromosome 3q nucleic acid sequence as including the chromosomal locus identified as TERC. Claim 12, depending on Claim 7, further defines the targeted centromere nucleic acid sequence as centromere 3 (CEP3). Claim 17 further defines the method as comprising different methods of detecting, including FISH. Claim 18 further defines the sample as comprising cells derived from at least a pap smear or a thin layer cytology specimen. Claim 19 further states that at least 50 cells are examined.

72. Upon information and belief, Quest's Cervical Cancer TERC Test meets all of the limitations of Claim 1 of the '270 patent. More specifically, it is a FISH test that uses a 3q probe and a probe to a centromere to examine and detect increased numbers or "gains" in both the 3q region and the centromere and uses this information to report if the samples is abnormal or normal. In this regard, Quest's Cervical Cancer TERC Test includes the following steps: (1) hybridizing a first nucleic acid sequence to a target nucleic acid sequence on chromosome 3q; (2) hybridizing a second nucleic acid sequence to a target nucleic acid sequence on a centromere; (3) detecting a hybridization signal of the first and the second nucleic acid sequence, wherein the hybridization signal of said first and the second nucleic acid sequences is indicative of chromosomal copy

number for chromosome 3q and the control chromosome; and (4) scoring the chromosomal copy number for chromosome 3q and centromere. In addition, upon information and belief, Quest's performance of their Quest Cervical TERC Test also meets the recited threshold of Claim 1 because many patients who have been reported as "negative" for chromosomal abnormalities under Quest's reporting cut-offs would also be reported as "negative for chromosomal abnormalities" under the reporting criteria recited in Claim 1 of the '270 Patent – thereby infringing this claim limitation. Furthermore, upon information and belief, Quest's performance of their Quest Cervical TERC Test also meets the recited threshold of Claim 1 because many patients who have been reported as "positive" for chromosomal abnormalities under Quest's reporting cut-offs would also be reported as "positive for chromosomal abnormalities" under the reporting criteria recited in Claim 1 of the '270 Patent – thereby infringing this claim limitation.

73. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 2, since Claim 2 depends from Claim 1, *see supra* Paragraph 72, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 2 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as 3q26.

74. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 3, since Claim 3 depends from Claim 1, *see supra* Paragraph 72, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 2 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as3q26.2.

75. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 4, since Claim 4 depends from Claim 1, *see supra* Paragraph 72, and Quest's

Cervical Cancer TERC Test meets the added limitation of Claim 4 that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to the targeted nucleic acid sequence of at least one of the chromosomal 3q loci being identified as EVI1, MDS1, TERC, APRM1, MYNN, LRRC34, LRRIQ4, LRRC31, SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI.

76. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 5, since Claim 5 depends from Claim 4, *see supra* Paragraph 72, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 5 that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to the targeted nucleic acid sequence of chromosomal 3q locus identified as TERC.

77. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 6, since Claim 6 depends from Claim 1, *see supra* Paragraph 72, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 6 that the centromere probes used in Quest's Cervical Cancer TERC Test hybridize to the centromere of chromosome 3 (CEN3/CEP3).

78. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 7, since Claim 7 depends from Claim 1, *see supra* Paragraph 72, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 7 that the determination of cell to be abnormal if the chromosomal copy number for both 3q and the centromere is greater than 2

79. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 8, since Claim 8 depends from Claim 7, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 8 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as 3q26.

80. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 9, since Claim 9 depends from Claim 7, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 9 in that the 3q probes used in Quest's Cervical Cancer TERC Test hybridizes to nucleic acid sequences at the chromosomal 3q locus identified as3q26.2.

81. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 10, since Claim 10 depends from Claim 7, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 10 that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to the targeted nucleic acid sequence of at least one of the chromosomal 3q loci being identified as EVI1, MDS1, TERC, APRM1, MYNN, LRRC34, LRRIQ4, LRRC31, SAMD7, LOC1000128164, SEC62, GPR160, PHC3, or PRKCI.

82. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 11, since Claim 11 depends from Claim 7, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 11 that the 3q probes used in Quest's Cervical Cancer TERC Test hybridize to the targeted nucleic acid sequence of chromosomal 3q locus identified as TERC.

83. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 12, since Claim 12 depends from Claim 7, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 12 that the centromere probes used in Quest's Cervical Cancer TERC Test hybridize to the centromere of chromosome 3 (CEN3/CEP3).

84. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 17, since Claim 17 depends from Claim 1, *see supra* Paragraph 78, and

Quest's Cervical Cancer TERC Test meets the added limitation of Claim 17 in Quest's Cervical Cancer TERC Test utilizes FISH as a method of detection.

85. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 18, since Claim 18 depends from Claim 1, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 18 in Quest's Cervical Cancer TERC Test detects cells derived from at least a pap smear, or a thin layer cytology specimen.

86. Upon information and belief, Quest's Cervical Cancer TERC Test also meets all the limitations of Claim 19, since Claim 19 depends from Claim 1, *see supra* Paragraph 78, and Quest's Cervical Cancer TERC Test meets the added limitation of Claim 19 in that at least 50 cells have been examined when performing Quest's Cervical Cancer TERC Test.

87. NeoDiagnostix is entitled to recover from Defendant the damages sustained by NeoDiagnostix as a result of Defendant's infringement of the '270 patent in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

88. NeoDiagnostix is also entitled to an injunction preventing all further sale or use of Quest's Cervical Cancer TERC Test , or any method claimed in the '270 patent for detecting chromosomal abnormalities.

JURY DEMAND

NeoDiagnostix hereby demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, NeoDiagnostix requests that this Court enter judgment against Defendant as to all Counts as follows:

A. An adjudication that Defendant has infringed the ‘099 patent, the ‘203 patent, and the ‘270 patent;

B. Preliminarily and permanently enjoining Defendant and its officers, employees, servants, and agents, and all persons in active concert with any of them, against any further acts of direct infringement or indirect infringement under 35 U.S.C. § 283, including without limitation making, using, offering to sell, and/or selling Quest’s Cervical Cancer TERC Test;

C. An award of damages to be paid by Defendant adequate to compensate NeoDiagnostix for Defendant's past infringement of the ‘099 patent, the ‘203 patent, and the ‘270 patent through the date of entry of judgment, including interest, costs, expenses and an accounting of all infringing acts including, but not limited to, those acts not presented at trial;

D. Finding the infringement by Defendant to be willful, and order it to pay three (3) times the amount of damages found or assessed, under 35 U.S.C. § 284;

E. A declaration that this case is exceptional under 35 U.S.C. § 285;

F. NeoDiagnostix’s attorneys’ fees, costs and interest incurred in this action; and

G. An award to NeoDiagnostix of such further relief at law or in equity as the Court deems just and proper.

Dated: March 23, 2017

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